

Effectiveness of Percutane Tibiale Nerve Stimulation (PTNS) treatment in children

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The goal of this study is to analyse the effect and safety of PTNS in 20 children with persistent overactive bladder complaints refractory to standard treatment

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Urinary tract signs and symptoms
Study type	Interventional

Summary

ID

NL-OMON43544

Source

ToetsingOnline

Brief title

Ped-PTNS

Condition

- Urinary tract signs and symptoms

Synonym

bladder overactivity, urinary incontinence

Research involving

Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: medische inspiratorprijs ZonmW

Intervention

Keyword: Children, Pediatric urology, PTNS, Urinary Incontinence

Outcome measures

Primary outcome

Outcome and differences in parameters measured on Frequency-volume charts: urgency, average bladder capacity, diaper weight, micturation frequency day/night, severity of incontinence. All parameters are measured at baseline, after 12 weeks and after 16 weeks and compared

Secondary outcome

Outcome and differences in quality of life scores at baseline, 12 weeks and 16 weeks

Study description

Background summary

Introduction

Approximately 6-9% of school-aged children girls suffer from overactive bladder with or without urinary incontinence. From the age of 6-7 years old other treatments can be started besides conservative methods like urotherapy, pelvic floor training and or medical/psychological treatment (Austin, Bauer et al. 2014).

For many children, these are successful treatments (Mulders, Cobussen-Boekhorststraat et al 2011; Vijverberg, Stortelder et al 2011; Van Gool, de Jong et al 2013). For the group of children in which this therapy is not successful (20%), more experimental treatments can be considered, like for example botulinum toxin treatment (Blackburn, Jones et al. 2013). This treatment requires anesthesia. The effect of Botuline toxine is approximately 6-9 months after which symptoms frequently recur.

Percutaneous Tibial Nerve Stimulation (PTNS) or stimulation of the posterior tibial nerve through a needle in the skin, is for some years now a successful treatment in adults with overactive bladder syndrome (OAB) (Biemans and van Balken 2013, Gaziev, Topazio et al. 2013). There is recent literature showing that this treatment in children with OAB symptoms is successful and can be used safely (Hoebeke, Renson et al 2002; Capitanucci, Camanni et al. 2009).

Study objective

The goal of this study is to analyse the effect and safety of PTNS in 20 children with persistent overactive bladder complaints refractory to standard treatment

Study design

Material and Method

PTNS treatment is a minimally invasive treatment, and can be applied in children with OAB symptoms.

During the treatment, which is given by a nurse specialist, stimulation finds place of the tibial nerve by means of a needle into the skin. Here, the wrong or undesirable sensations from the pelvis can be blocked by providing an electrical signal to a nerve branch at the ankle. This nerve branch is closely connected with the nerves of the organs in the pelvis, such as bladder, rectum and sphincter. By stimulating the tibial nerve, the behavior of the nerves that run to the pelvic organs, affects positive.

The treatment consists of a stimulation of half an hour, for 12 weeks in the outpatient department of urology.

For this effectiveness study 20 children from two centers will be treated, Radboud University Nijmegen Medical Centre, outpatient pediatric urology, Nijmegen and Noorderboog hospital, drying bed and pelvis center, Meppel

Intervention

during 12 weeks , participants come for 30 minutes for the nerve tibialis stimulation.

Study burden and risks

- 12 weeks for 1/2 hour to the hospital can be a burden for children and parents
- when puncturing a needles hurts, this can be stressfull for the child

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Children (2-11 years)

Inclusion criteria

- * age >8 en <16 year
 - * complaints of bladder overactivity
 - * patients with functional bladder capacity < 65 % of estimated bladder capacity for age (Austin, Bauer et al. 2014) .
 - * previous unsuccessful treatments for overactive bladder: urotherapy, pelvic floor therapy, medical / psychological treatment:
 - * clean urine sediment
 - * signed informed consent
- Under the age of 12 both parents, Above the age of 12 both parents and patient

Exclusion criteria

- congenitale urological anomalies, except for mild urethral valves and meatus operation (assessed by pediatric urologist)
- voiding problems due to neurogenic case
- continuing of anticholinergics
- untreated or inadequately treated obstipation
- pacemaker or implanted defibrillator
- Prone to excessive bleeding
- Pregnancy
- previous PTNS treatment
- previous botuline toxine intravesical treatment for overactive bladder within 6 months of the

start of the study

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 10-03-2017

Enrollment: 20

Type: Actual

Medical products/devices used

Generic name: Percutane Tibiale Nerve Stimulation through a needle

Registration: Yes - CE intended use

Ethics review

Approved WMO

Date: 10-01-2017

Application type: First submission

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date: 16-10-2017

Application type: Amendment

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL55958.091.15